

§ 177.1615

hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.1 of the table in §177.1520(c). Such chlorinated polyethylene contains a maximum of 60 percent by weight of total chlorine, as determined by ASTM 1method D1303-55 (Reapproved 1979), "Standard Test Method for Total Chlorine in Vinyl Chloride Polymers and Copolymers," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), and has a 7.0 percent maximum extractable fraction in *n*-hexane at 50 °C, as determined by the method described in §177.1520(d)(3)(ii).

(b) Chlorinated polyethylene may be used in contact with all types of food, except that when used in contact with fatty food of Types III, IV-A, V, VII-A, and IX described in table 1 of §176.170(c) of this chapter, chlorinated polyethylene is limited to use only as a modifier admixed at levels not exceeding 15 weight percent in plastic articles prepared from polyvinyl chloride and/or from vinyl chloride copolymers complying with §177.1980.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 59 FR 14550, Mar. 29, 1994]

§ 177.1615 Polyethylene, fluorinated.

Fluorinated polyethylene, identified in paragraph (a) of this section, may be safely used as food-contact articles in accordance with the following prescribed conditions:

(a) Fluorinated polyethylene food-contact articles are produced by modifying the surface of polyethylene articles through action of fluorine gas in combination with gaseous nitrogen as an inert diluent. Such modification affects only the surface of the polymer, leaving the interior unchanged. Fluorinated polyethylene articles are manufactured from basic resins containing not less than 85 weight-percent of polymer units derived from ethylene and identified in §177.1520 (a)(2) and (3)(i).

(b) Fluorinated polyethylene articles conform to the specifications and use

21 CFR Ch. I (4-1-02 Edition)

limitations of §177.1520(c), items 2.1 and 3.1.

(c) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields fluoride ion not to exceed 5 parts per million calculated on the basis of the volume of food held by the food-contact article.

[48 FR 39057, Aug. 29, 1983]

§ 177.1620 Polyethylene, oxidized.

Oxidized polyethylene identified in paragraph (a) of this section may be safely used as a component of food-contact articles, in accordance with the following prescribed conditions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.3 of the table in §177.1520(c). Such oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry, contains a maximum of 5 percent by weight of total oxygen, and has an acid value of 9 to 19.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods described in §177.1330(c), except that net acidified chloroform-soluble extractives from paper and paperboard complying with §176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in §176.170(d) (5)(iii)(b) of this chapter. If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by such regulations.

(NOTE: In testing the finished food-contact article, use a separate test sample for each extracting solvent.)

(c) The provisions of this section are not applicable to oxidized polyethylene used as provided in §§175.105 and 176.210 of this chapter, and §177.2800. The provisions of paragraph (b) of this section are not applicable to oxidized polyethylene used as provided in §§175.125 and 176.170(a)(5) of this chapter and §177.1200.

§ 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in §177.1315(b)(3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c)(1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitations further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (e)(4) subject to the limitations prescribed:

LIST OF SUBSTANCES AND LIMITATIONS

(i) Base sheet:

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid, pyromellitic dianhydride. The level of pyromellitic dianhydride shall not exceed 0.5 percent by weight of the finished copolymer which may be used under conditions of use E through H as described in table 2 of §176.170(c) of this chapter.

Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid and dimethyl isophthalate or isophthalic acid with ethylene glycol. The finished copolymers contain either: